

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY (Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44bis)

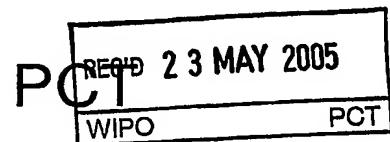
Applicant's or agent's file reference 2003P18385WO	FOR FURTHER ACTION		See item 4 below
International application No. PCT/EP2004/012925	International filing date (<i>day/month/year</i>) 15 November 2004 (15.11.2004)	Priority date (<i>day/month/year</i>) 23 December 2003 (23.12.2003)	
International Patent Classification (8th edition unless older edition indicated) See relevant information in Form PCT/ISA/237			
Applicant PAUL SCHERRER INSTITUT			

<p>1. This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44 bis.1(a).</p> <p>2. This REPORT consists of a total of 6 sheets, including this cover sheet.</p> <p>In the attached sheets, any reference to the written opinion of the International Searching Authority should be read as a reference to the international preliminary report on patentability (Chapter I) instead.</p>																								
<p>3. This report contains indications relating to the following items:</p> <table> <tbody> <tr> <td><input checked="" type="checkbox"/></td> <td>Box No. I</td> <td>Basis of the report</td> </tr> <tr> <td><input type="checkbox"/></td> <td>Box No. II</td> <td>Priority</td> </tr> <tr> <td><input type="checkbox"/></td> <td>Box No. III</td> <td>Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</td> </tr> <tr> <td><input type="checkbox"/></td> <td>Box No. IV</td> <td>Lack of unity of invention</td> </tr> <tr> <td><input checked="" type="checkbox"/></td> <td>Box No. V</td> <td>Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</td> </tr> <tr> <td><input type="checkbox"/></td> <td>Box No. VI</td> <td>Certain documents cited</td> </tr> <tr> <td><input type="checkbox"/></td> <td>Box No. VII</td> <td>Certain defects in the international application</td> </tr> <tr> <td><input type="checkbox"/></td> <td>Box No. VIII</td> <td>Certain observations on the international application</td> </tr> </tbody> </table> <p>4. The International Bureau will communicate this report to designated Offices in accordance with Rules 44bis.3(c) and 93bis.1 but not, except where the applicant makes an express request under Article 23(2), before the expiration of 30 months from the priority date (Rule 44bis .2).</p>	<input checked="" type="checkbox"/>	Box No. I	Basis of the report	<input type="checkbox"/>	Box No. II	Priority	<input type="checkbox"/>	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability	<input type="checkbox"/>	Box No. IV	Lack of unity of invention	<input checked="" type="checkbox"/>	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement	<input type="checkbox"/>	Box No. VI	Certain documents cited	<input type="checkbox"/>	Box No. VII	Certain defects in the international application	<input type="checkbox"/>	Box No. VIII	Certain observations on the international application
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PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY



To:

W/T

see form PCT/ISA/220

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY
(PCT Rule 43bis.1)**

		Date of mailing (day/month/year) see form PCT/ISA/210 (second sheet)
Applicant's or agent's file reference see form PCT/ISA/220		FOR FURTHER ACTION See paragraph 2 below
International application No. PCT/EP2004/012925	International filing date (day/month/year) 15.11.2004	Priority date (day/month/year) 23.12.2003
International Patent Classification (IPC) or both national classification and IPC G01N33/68, G01N33/566		
Applicant PAUL SCHERRER INSTITUT		

1. This opinion contains indications relating to the following items:

- Box No. I Basis of the opinion
- Box No. II Priority
- Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- Box No. IV Lack of unity of invention
- Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or Industrial applicability; citations and explanations supporting such statement
- Box No. VI Certain documents cited
- Box No. VII Certain defects in the international application
- Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA"). However, this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of three months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA:	Authorized Officer
 European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	GONCALVES MAUGER, M Telephone No. +49 89 2399-8127
 Deutsches Patentamt - Europäisches Patentamt - European Patent Office	

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/EP2004/012925

Box No. I Basis of the opinion

1. With regard to the language, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
 - This opinion has been established on the basis of a translation from the original language into the following language , which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).
2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. type of material:
 - a sequence listing
 - table(s) related to the sequence listing
 - b. format of material:
 - in written format
 - in computer readable form
 - c. time of filing/furnishing:
 - contained in the international application as filed.
 - filed together with the international application in computer readable form.
 - furnished subsequently to this Authority for the purposes of search.
3. In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/EP2004/012925

**Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or
Industrial applicability; citations and explanations supporting such statement**

1. Statement

Novelty (N)	Yes:	Claims	1-16
	No:	Claims	
Inventive step (IS)	Yes:	Claims	1-16
	No:	Claims	
Industrial applicability (IA)	Yes:	Claims	1-16
	No:	Claims	

2. Citations and explanations

see separate sheet

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING
AUTHORITY (SEPARATE SHEET)**

International application No.

PCT/EP2004/012925

The following documents were cited in the search report:

- D1: TRANSDUCERS' 95 . EUROSENSORS IX, vol. 2, 25 - 29 June 1995, pages 487-490, XP010305158
- D2: THE 23RD. ANNUAL INTERNATIONAL CONFERENCE OF THE IEEE ENGINEERING IN MEDICINE AND BIOLOGY SOCIETY., OCT. 25 - 28, 2001, vol. 1 OF 4. CONF. 23, 25 October 2001 (2001-10-25), pages 733-736, XP010593479
- D3: MICROELECTRONIC ENGINEERING, NL, vol. 67-68, June 2003, pages 208-213, XP004428871
- D4: JOURNAL OF MOLECULAR RECOGNITION, vol. 9, 1996, pages 485-487, XP000886890
- D5: DISEASE MARKERS, vol. 18, no. 4, 2002, pages 185-191, XP009024573
- D6: FEBS LETTERS, vol. 515, no. 1-3, 27 March 2002, pages 29-34, XP004347736

1. The subject-matter of claim 1 is an assay chip for investigation of the functionality of non lipid molecules and their interactions with molecules comprising features a) to c).

The closes prior art, results from document D3, which discloses the assay chips comprising the features a) and b) (see abstract, figure 4 and page 213).

Thus the subject-matter of claim 1 is novel.

2. The feature differentiating the subject-matter of claim 1 from the disclosure in D3 is the biological effective layer deposited on the support layer and covering the plurality of nanopores (feature c) of claim 1).
- D6 describes lipid membrane bilayers supported on mica (see abstract and materials parts of the document). Mica is a solid support, and the immobilization of biomembranes on solid supports leads to a restricted fluidility of the the lipid bilayer and a structural disturbance of the membrane protein.

The subject-matter of claim 1 cannot be derived from the known prior art documents,

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING
AUTHORITY (SEPARATE SHEET)**

International application No.

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either taken alone or in combination.

The claimed assay chip offers an array of nanopores of macroscopic lateral dimension, and thus provides a supporting area to stabilize the biological effective layer and pores in a high density in which the biological effective layer remains fully fluid. This assay chip offers a versatile system for various applications like drug screening and functional protein analysis (see also pages 6 and 7 of the description).

The assay chip of claim 1, has a biological effective layer as a membrane having high and reliable stability in a manner that its fluidity is sustained in order to integrate a non lipid molecule into said layer preserving its full biological functionality. Due to this unexpected additional effect, the presence of an inventive step can be acknowledged.

3. The dependent claims 2-12 add features to the chip of claim 1 and thus also relate to novel and inventive subject-matter.
4. The above comments also apply to the subject-matter of independent claims 13, 14, 15 and 16, referring to uses of the assay chip of claim 1.
5. The dependency of claims 15 and 16 should be corrected to "assay chip according to claims 1 to 12" for the sake of clarity.